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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/463,586	04/24/00	VALLERI	M 515-4183

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EXAMINER	
PULLIAM,A	
ART UNIT	PAPER NUMBER
1615	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/463,586	Applicant(s) VALLERI, MAURIZIO	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication app ars on th cov r sh t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 13-18* is/are rejected.

7)☐ Claim(s) *11 and 12* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of the Declaration, Preliminary Amendment A, and the Information Disclosure Statement, received April 24, 2000, April 24, 2000, and May 30, 2000, respectively.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 7-10, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 2, the language in these claims is confusing because they are improperly worded Markush claims. Section 2173.05 (h), part I of the MPEP states that a Markush group recites members as being "selected from the group consisting of A, B, and C." *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925). The MPEP further states that it is improper to use the term "comprising" instead of "consisting of." *Ex parte Dotter,* 12 USPQ 382 (Bd. App. 1931). Appropriate correction is required.

Claim 13 recites the limitations "the colloidal silica", "the citric acid", "the sodium saccharin", "the time required", "the appropriate speed", "the remaining part of the mannite", "the mixture", "the vitamin D_3", "the rest of the preparation", and "the

granulate" in claim 1. There is insufficient antecedent basis for these limitations in the claim. Appropriate correction is required.

Claim 14 recites the limitations "the vitamin D_3", "the sorbitol", "the required time", "the appropriate speed", "the appropriate weight", and "the desired tablets" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Regarding claim 7, the phrase within the parentheses renders the claim indefinite because it is unclear whether the limitation(s) is part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 8, the phrase within the parentheses renders the claim indefinite because it is unclear whether the limitation(s) is part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 9 and 10, "E110" is considered vague and indefinite, because it is unclear what this component is. It is requested that this component be better defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 8, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by FR-A-2 073 271 (FR '271). FR '271 discloses a composition comprising vitamin D associated to a calcium salt, as well as paraffin oil. Specifically, in the example on page 2, FR '271 discloses a composition comprising vitamin D_2, calcium carbonate, paraffin oil, and Tesal, which is a propylene glycol derivative. Additionally, the reference does not disclose the amounts of vitamin D and calcium salt in the same manner claimed by applicant, and therefore there is no means for a comparison. Therefore, the burden is shifted to applicant to prove that the two formulations are patentably distinct. Lastly, FR '271 teaches that their composition is useful for treating calcium deficiencies (p 2, l 31). Therefore, the disclosure of FR '271 anticipates the limitations of claims 1, 2, 4, 5, 7, 8, 15, and 17.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 588 539 A to Silver. Silver discloses a pharmaceutical composition which comprises either vitamin D_2 or vitamin D_3 , excipients, and calcium phosphate (p 5, claims 1 and 6). Furthemore, Silver calls for the inclusion of excipients, and specifically teaches that polyethylene glycol can be included as a stabilizer (p 5, claim 5). The reference does not disclose the amounts of vitamin D and calcium salt in the same manner claimed by applicant, and therefore there is no means for a comparison. Therefore, the burden is shifted to applicant to prove that the two formulations are patentably distinct. Therefore, the disclosure anticipates the limitations of claims 1-7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR '271 as discussed above. FR '271 is discussed as teaching a composition comprising a calcium salt, vitamin D, propylene glycol, and paraffin oil for the treatment of calcium deficiencies. FR '271 does not specifically disclose all of the possible calcium salts which can be used in their invention. However, the reference does state that any calcium salt which can be tolerated by the organism can be employed. It is the position of the examiner that one of ordinary skill in the art would have been motivated to use any well known pharmaceutically acceptable salt in the composition, based on the teachings of FR '271. Furthermore, FR '271 does not specifically teach that vitamin D_2 or vitamin D_3 can be used. However, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use either form of vitamin D based on the teachings of FR '271. Lastly, it is the position of the examiner that one skilled in the pharmaceutical art know that osteoporosis is a condition called by a calcium deficiency, and therefore, any composition which treats calcium deficiencies inherently treats osteoporosis as well. In conclusion, one of ordinary skill in the art would have been motivated to make a composition comprising any well known pharmaceutically acceptable calcium salt and vitamin D to make a

formulation for the treatment of calcium deficiencies and osteoporosis. The expected result would be a formulation which is successful in these treatments. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-8, and13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR-A-2 724 844 (FR '844). FR '844 discloses a composition comprising a calcium salt and and vitamin D. More specifically, FR '844 teaches that the calcium salt can be selected from the group including calcium carbonate, calcium phosphate, calcium citrate, calcium gluconate, calcium lactate, and others (p 11, claim 2). Additionally, FR '844 teaches that the vitamin D can be in the form of vitamin D_2 or vitamin D_3 (p 11, claim 3). FR '844 also teaches the presence of many well known additives, including binders, lubricants, and flavor agents. The reference also teaches the formulation in many different forms, including a sachet (p 13, claim 13). FR '844 also teaches a method to produce the formulation, comprising granulating the components and mixing them together, prior to making the final dosage form (p 13, claim 14). FR '844 does not teach all of the specific additives claimed by applicant. However, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any well known additives in the formulation. Furthermore, it is the position of the examiner that FR '844 discloses the generic concept of applicant's invention, and the burden is shifted to applicant to show a patentable difference. Additionally, the reference does not disclose the amounts of vitamin D and calcium salt in the same manner claimed by

applicant, and therefore there is no means for a comparison. Therefore, the burden is shifted to applicant to prove that the two formulations are patentably distinct. One of ordinary skill in the art would have been motivated to create a sachet formulation comprising particles of vitamin D and a calcium salt, as well as well known additives, for the treatment of calcium deficiency, based on the teachings of FR '844. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

Claims 9-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Additionally, these claims must be rewritten to overcome any 112 rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

AEP
June 15, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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